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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,077	06/28/2006	Thomas G. Schlagheck	448-67 PCT US	4740

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EXAMINER
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ROGERS, JUNE MARIE

ART UNIT	PAPER NUMBER
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1612

MAIL DATE	DELIVERY MODE
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06/25/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/527,077	<b>Applicant(s)</b> SCHLAGHECK, THOMAS G.	
	<b>Examiner</b> JUNE ROGERS	<b>Art Unit</b> 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 April 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 50-76 is/are pending in the application.
- 4a) Of the above claim(s) 50-62 and 67-76 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 50-62 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>05/09/2007</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election with traverse of Group II, claims 63-66 and the specie morphine in the reply filed on April 29, 2003 is acknowledged. The traversal is on the ground(s) that Applicant disagrees with the Examiner's assertion that the inventions lack unity. This is not found persuasive because Examiner has cited Caruso, as evidence that the instant claims do not make a contribution over the prior art. Caruso discloses an analgesic drug in extended release form in combination with NMDA in an immediate release form. Caruso teaches the combination in being in a drug delivery device, this device having "deposit of the drug" in the layers (see claims 1-16); Thus reading on the limitations of the extended release and immediate forms. It is noted the Applicant appears to emphasize the topical nature of Caruso invention; however, Applicant claims are drawn generically to a composition.

The requirement is still deemed proper and is therefore made ***FINAL***.

Claims 50-62 and 67-76 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on April 29, 2008.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 63 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "substantially" in claim 63 is a relative term which renders the claim indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. .

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 63-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caruso et al. "Dextromethorphan, an NMDA-receptod antagoninist enhances the

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analgesic properties of morphine” Inflammopharmacology vol. 8, No.2, pp. 161-173, in view of Roswell USP 4,574,080.

Caruso et al. teaches discloses a composition comprising the NMDA receptor antagonist, dextromethorphan in combination with morphine; the components being present in a 1:1 ratio (page 162, first paragraph). Caruso et al. teaches dextromethorphan enhances the analgesic properties of morphine (page 162, first paragraph and page 172, see discussion).

Caruso et al. differs insofar as it does not disclose dextromethorphan in an immediate release carrier or morphine in an extended release carrier

Roswell et al. teaches it is advantageous to combine two active substances, either to obtain a combination effect of improve patient compliance (col. 2, lines 6-8)

Roswell et al. discloses pharmaceutical compositions comprising compositions containing active agents in which one is present in an extended release form and another is present in an immediate release form, wherein the active substance in immediate release form is coated on the surface or the extended release coating (see claim 1). Roswell et al. discloses the extended release form comprises a base material selected from cellulose derivatives, acrylic polymers, vinyl polymers, and other high molecular synthetic polymers (see claims 1,6 and 12). Roswell teaches suitable active substance used in the extended release and the control release formulations may be found among various therapeutic groups such as analgesics (col. 8, lines 35-49).

Roswell et al. differs insofar as it does not disclose the specific active agents to be dextromethorphan and morphine.

"[w]hen a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious" KSR v. Teleflex, 127 S. Ct. 1727, 1740 (2007) (quoting Sakraida v. A.G. Pro., 425 U.S 273, 282 (1976)). "[W]hen the question is whether a patent is claiming the combination of elements of prior art is obvious", the relevant question is "whether the improvement is more than the predictable use of prior art elements according to their established functions." (Id.). Addressing the issue of obviousness, the Supreme Court noted that the analysis under 35 USC 103 "need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." KSR v. Teleflex, 127 S. Ct. 1727, 1741 (2007). The Court emphasized that "[a] person of ordinary skill is.....a person of ordinary creativity, not an automaton." Id. at 1742.

Consistent with this reasoning it would have been obvious to have formulated that composition of Caruso in an extended release /immediate release formulation in order to obtain a combination effect (which is taught by primary reference to be the enhancement of the analgesic properties of morphine) or to increase patient compliance, as taught by the secondary reference.

### ***Conclusion***

No claims allowed.

***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JUNE ROGERS whose telephone number is (571)270-3497. The examiner can normally be reached on M-F 9-6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fred Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Juné M. Rogers

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612